

## Carchman, Loreen

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**From:** Roethig, Hans-Juergen  
**Sent:** Friday, February 09, 2001 2:16 PM  
**To:** Oey, Jan; Carchman, Loreen; Kinser, Robin D.; Lau, Raymond W.; Nelson, Bettie L  
**Cc:** Walk, Roger A.  
**Subject:** RE: Tentative timelines for the Pilot Study

Dear Jan,

I think we should not accept the new clinical timelines! If we accept this procedure we will not have a report by the end of this year. Due to the urgent need of the information from this study we really have to push Covance now! The information is not only needed for the TES but also for Accord, cigarette burn study and SCoR.

Taking into account the standard times for study planning and organization I do not see any smoker being enrolled in the large TES before summer-autumn 2002.

Best regards

Hans

-----Original Message-----

**From:** Oey, Jan  
**Sent:** Friday, February 09, 2001 1:52 PM  
**To:** Carchman, Loreen; Kinser, Robin D.; Lau, Raymond W.; Nelson, Bettie L; Roethig, Hans-Juergen; Tricker, Anthony  
**Cc:** Walk, Roger A.  
**Subject:** FW: Tentative timelines for the Pilot Study

FYI

-----Original Message-----

**From:** Jill Schultz (SMTP:jill.schultz@Covance.Com)  
**Sent:** Friday, February 09, 2001 9:46 AM  
**To:** Jill Schultz; Jan.Oey@pmusa.com  
**Cc:** Roger.A.Walk@pmusa.com  
**Subject:** Re: Tentative timelines for the Pilot Study

Please see correction below in bold for item 4. Jill

>>> Jill Schultz 2/9/01 7:50:34 AM >>>

Dear Jan,

The following timeline was discussed with the CRU and may be more feasible:

- (1) Analytical validation complete: End of May 2001
- (2) Start Pilot Study (enrollment): July 2001 (Final protocol June 11, IRB June 25)
- (3) End of clinical part of Pilot Study: End of Sept 2001/Early Oct 2001
- (4) Clinical and analytical report: January 2001 (usually 12 weeks after CRFs are received by Data Management).

Please note that these are tentative dates and may be revised based on when the analytical validations are complete. Please contact me if you have any questions.

Thank you,

Jill

>>> "Oey, Jan" <Jan.Oey@pmusa.com> 2/6/01 5:05:30 PM >>>  
Dear Jill,

Please check whether or not my estimate of timelines as below will work?

- (1) Analytical validation complete: May 2001
- (2) Start Pilot Study (enrollment: June 2001
- (3) End of clinical part of Pilot Study: August 2001
- (4) Clinical and analytical report: December 2001

Moreover, do you think that the "Draft No.2 Research Protocol" will be ready for reviewing before the Meeting at Madison?

Best regards,

Jan

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